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10/575,087	05/22/2006	James Fuller	092633-0107	8717

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
HORNING, MICHELLE S	

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1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,087	FULLER, JAMES	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85-130* is/are pending in the application.

4a) Of the above claim(s) *94, 95, 104-108, 114, 115, 117-123, 129, 130* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-93,96-103,109-113,116 and 124-128* is/are rejected.

7)☒ Claim(s) *85,109 and 116* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/10/2006, 2/15/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 4/26/2010.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 4/26/2010 is acknowledged. The traversal is on the ground(s) that the three groups of claims are linked by a special technical feature as required by PCT Rule 13.2. Moreover, the claims are directed to "a product and process of use of said product". This is not found persuasive because as noted in the Requirement for Restriction, WO 2002/31137 describes the claimed invention and thus, the claimed invention is not a contribution over the prior art. More specifically, this reference discloses the use of a construct for the expression of a heterologous coding sequence in the pCMVkm-Luciferase in which the *entire* sequence of Intron A was substituted with the Intron I from the rabbit beta-globin gene (see Example 2, p. 35). Page 5 of this reference discloses an embodiment wherein exon 2 may be included in the construct. See instant claim 109.

The requirement is still deemed proper and is therefore made FINAL.

Claims 94, 95, 104-108,114, 115, 117-123, 129 and 130 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/26/2010.

Claims 85-93, 96-103, 109-113, 116 and 124-128 are under current examination.

Applicant's election of species: A. SEQ ID NO: 5; B. SEQ ID NO: 8; C. rat insulin intron A sequence; D. rabbit beta-globin gene; E. SEQ ID NO: 10; F. hTPAsp; G.

HBsAg; H. gold particle; and, I. ADP ribosylating bacterial subunit A and B is acknowledged.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See p. 17; this is a single example and all hyperlinks in the specification should be properly addressed.

The use of the trademark POWDER JECT (p. 54) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Note that POWDER JECT is merely an example and all trademarks in the specification should be properly addressed.

Claim Objections

Claims 85, 109 and 116 are objected to because of the following informalities: this claim reads on "a hCMV" instead of "an hCMV"; see part (a). Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 109-113 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/36792 (hereinafter as "Catchpole", published 10/5/2002-cited by IDS).

Claims 109-113 are drawn to (in part): A nucleic acid construct comprising a chimeric promoter sequence and a cloning site for insertion of a coding sequence in operable linkage with the chimeric promoter, wherein the chimeric promoter sequence comprises:

(a) an hCMV immediate early promoter sequence;

(b) exon 1 and at least a part of exon 2 of the hCMV major immediate early gene; and

(c) a heterologous intron provided in place of the intron A region of the hCMV major immediate early gene.

Catchpole describes DNA vectors derived from hCMV immediate early gene which includes exon 1 and a heterologous intron that replaces the natural intron A of HCMV IE1 (see p. 2, lines 1-8). The author further describes including a part of HCMV IE1 exon 2 (p. 4, lines 3-10). Note that this meets "a chimeric promoter" as defined by parts (a)-(c) in claim 109. Catchpole describes including restriction sites in the vector for the insertion of a heterologous coding sequence and operably linking a sequence encoding a recombinant polypeptide to the promoter (see p. 4, lines 35+ to p. 6, lines 1-10); this meets the limitation of "cloning site" as required by claim 109. The author provides coating the vector onto a gold bead (elected species H), delivering the vector via a gene gun, a syringe or a needle-free delivery approach and using a pharmaceutically acceptable carrier (see p. 16 and claim 11 of this reference and instant claims 110-113).

Thus, this reference anticipates the rejected claims.

Claim 124 is rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (*Gene Therapy*, 2001-see form 892) as further evidenced by Moriarty et al. (*PNAS*, 1981-see form 892) and Dean et al. (*Expt. Cell Res.*, 1999-see form 892).

The claim is drawn to: a nucleic acid construct comprising:

(i) a promoter sequence;

(ii) a coding sequence operably linked to the promoter sequence (i); and

(iii) an enhancer sequence 3' of and operably linked to the coding sequence (ii);

wherein the enhancer sequence (iii) is derived from a 3'UTR of an HBsAg sequence or a 3'UTR of a simian CMV immediate early gene sequence, and the coding sequence (ii) is heterologous to the 3' enhancer sequence.

Li et al. describe a nucleic acid construct comprising a promoter sequence, a coding sequence and a 72 bp simian virus 40 (SV40) enhancer wherein the coding sequence is heterologous to the SV40; see abstract and Figures 2 and 3, p. 496.

Moriarty et al. is cited for using a SV40 which comprises the SV40 enhancer homologous to that of SEQ ID NO: 8 (elected species B).

Dean et al. is cited to show that the 72 bp element in the SV40 enhancer is inherently found in the 3' UTR of the early gene sequence. See p. 714, Figure 2 and part (iii) of claim 124.

Thus, this reference anticipates the rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 125-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (Gene Therapy, 2001-see form 892) as applied to claim 124 above, and further in view of WO 02/36792 (hereinafter as "Catchpole", published 5/10/2002-cited by IDS) as further evidenced by Moriarty et al. (*PNAS*, 1981-see form 892) and Dean et al. (*Expt. Cell Res.*, 1999-see form 892).

The claims are further drawn to (in part): coated particles which particles are coated with a nucleic acid construct, a dosage receptacle for a particle mediate delivery device comprising coated particles, a particle mediated delivery device loaded with coated particles and a pharmaceutical preparation comprising a nucleic acid construct and a pharmaceutically acceptable excipient.

As noted above, Li et al. describe a nucleic acid construct comprising a promoter sequence, a coding sequence and a simian virus 40 (SV40) enhancer wherein the coding sequence is heterologous to the SV40; see abstract and Figures 2 and 3, p. 496. It is further noted that the authors describe administering such construct to a subject; see p. 495, col. 1, para. 3.

Li et al. do not explicitly describe the following: coated particles which particles are coated with a nucleic acid construct (claim 125), a dosage receptacle for a particle

mediate delivery device comprising coated particles (claim 126), a particle mediated delivery device loaded with coated particles (claim 127) and a pharmaceutical preparation comprising a nucleic acid construct and a pharmaceutically acceptable excipient (claim 128). Moriarty et al. is cited for using a SV40 which comprises the SV40 enhancer homologous to that of SEQ ID NO: 8 (elected species B). Dean et al. is cited to show that the 72 bp element in the SV40 enhancer is inherently found in the 3' UTR of the early gene sequence. See p. 714, Figure 2 and part (iii) of claim 124.

Catchpole provides coating the vector onto a gold bead (elected species H; see instant claim 125), delivering the vector via a gene gun, a syringe or a needle-free delivery approach (see claims 126 and 127) and using a pharmaceutically acceptable excipient (see instant claim 128); see p. 16 and claim 11 of this reference disclosing the claim limitations of claims 125-128.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the use of coated particles in a pharmaceutical preparation comprising a pharmaceutically acceptable excipient and the related dosage receptacle or delivery device in the teachings taught by Li et al. One would have been motivated to do so for the gain of optimizing results. There would have been a reasonable expectation of success, given such the use of coated particles and related dosage receptacles or delivery device are commonly used and widely known as demonstrated by the prior art. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claims 85-93, 96-102 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of WO 02/36792 (hereinafter as "Catchpole", published 5/10/2002-cited by IDS), WO 02/031137 (hereinafter as "Thudium"-cited by IDS), Li et al. (Gene Therapy, 2001-see form 892), US Patent 6165477 (hereinafter as "Ivy"), and Palmiter et al. (*PNAS*, 1991) as further evidenced by Moriarty et al. (*PNAS*, 1981-see form 892), Dean et al. (*Expt. Cell Res.*, 1999-see form 892), PGPUB 20030124523 (hereinafter as "Asselbergs", see form 892) and PGPUB 20030175711 (hereinafter as "Renner"; see form 892).

Claim 85 and its dependent claims are drawn to (in part): A nucleic acid construct comprising:

(i) a chimeric promoter sequence which comprises:

(a) an hCMV immediate early promoter sequence;

(b) exon 1 and at least a part of exon 2 of the hCMV major immediate early gene; and

(c) a heterologous intron provided in place of the intron A region of the hCMV major immediate early gene;

(ii) a coding sequence in operable linkage with the chimeric promoter;

(iii) a non-translated leader sequence which is selected from the HBVpreS2 antigen sequence, HBV e-antigen sequence and HSV type 2gD antigen sequence and which is in operable linkage with the chimeric promoter; and

(iv) an enhancer sequence which is derived from a 3' untranslated region (UTR) of a HBsAg sequence or of a simian CMV immediate early gene sequence, which is in

operable linkage with the chimeric promoter and which is downstream of the coding sequence.

Claim 116 is drawn to (in part): a purified isolated chimeric promoter sequence which comprises:

(a) an hCMV immediate early promoter sequence;

(b) exon 1 and at least a part of exon 2 of the hCMV major immediate early gene; and

(c) a heterologous intron provided in place of the intron A region of the hCMV major immediate early gene.

Catchpole describes DNA vectors derived from hCMV immediate early gene which includes exon 1 and a heterologous intron that replaces the natural intron A of HCMV IE1 (see p. 2, lines 1-8). The author further describes including a part of HCMV IE1 exon 2 (p. 4, lines 3-10). Note that this meets "a chimeric promoter" as defined by at least parts (a)-(c) in claim 85 and the sequence comprising structural limitations of claim 116. Catchpole describes including restriction sites into the vector for the insertion of a heterologous coding sequence and operably linking a sequence encoding a recombinant polypeptide to the promoter (see p. 4, lines 35+ to p. 6, lines 1-10 and part (ii) of claims 85 and claim 90). The author provides coating the vector onto a gold bead (elected species H), delivering the vector via a gene gun, a syringe or a needle-free delivery approach and using a pharmaceutically acceptable excipient (see p. 16 and claim 11 of this reference and instant claims 96-102).

Catchpole does not describe using a non-translated leader sequence which is HBVpreS2 antigen sequence (see claim 85, part (iii)), an enhancer sequence derived from 3'UTR simian CMV immediate early gene sequence (see claim 85, part (iv)), a rabbit beta-globin gene (claim 87, part (ii)), an HBVsAg antigen (elected species G), the enhancer sequence which is the sequence set forth by SEQ ID NO: 8 (elected species B and claim 86, part (iv), a heterologous intron that is the rat insulin intron A (elected species C), a human tissue plasminogen activator secretion signal peptide (elected species F) or a DNA in *purified* form (see claim 116).

Thudium discloses the use of a construct for the expression of a heterologous coding sequence in the pCMVkm-Luciferase in which the rabbit beta-globin gene was incorporated (see Example 2, p. 35); this meets the limitation of further incorporating one or more sequences which is a rabbit beta-globin gene (claim 87, part (ii)). The authors disclose that when the optimized rabbit beta-globin gene was used, this construct showed 4 times higher in the expression of p55 gag as compared to the parent vector; given the successful expression of p55 gag, this gene must be in operable linkage with the chimeric promoter. Note that p55 gag meets the limitation of a viral antigen (see claims 90-92) and a construct. The author also provides that the polypeptide sequences encoding proteins may include HBV antigens including the sAg/preS2 combination (see p. 21, para. 1; instant claims 85 (iii) and (iv) and 91-93; and elected species G). The author further describes techniques for isolating DNA (p. 23, para. 3 as required by claim 116). Asselbergs is cited for teaching the sequence set forth by SEQ ID NO: 10 which inherently encodes the rabbit beta-globin gene (see SEQ

ID NO: 1 of this application; elected species E). Renner is cited for teaching the sequence set forth by SEQ ID NO: 5 which inherently encodes HBVpreS2 (see SEQ ID NO: 133 of this application; elected species A).

Li et al. describe a nucleic acid construct comprising a promoter sequence, a coding sequence and a simian virus 40 (SV40) enhancer wherein the coding sequence is heterologous to the SV40; see abstract and Figures 2 and 3, p. 496. It is further noted that the authors describe administering such construct to a subject; see p. 495, col. 1, para. 3. The authors disclose that incorporation of this enhancer enhances gene expression (see title). Moriarty et al. is cited for using a SV40 which comprises the SV40 enhancer homologous to that of SEQ ID NO: 8 (elected species B). Dean et al. is cited to show that the 72 bp element in the SV40 enhancer is inherently found in the 3' UTR of the early gene sequence. See p. 714, Figure 2.

Ivy teaches using the human tissue plasminogen activator secretion signal sequence for secretion of protein products from Drosophila cells so that the secreted products can be easily purified and prepared as a vaccine (col. 6, lines 40+).

Palmiter et al. teaches that heterologous introns can enhance expression of transgenes in mice (see title). The authors provide that insertion of heterologous intron A of the rat insulin II gene increased expression by 75-fold (p. 480, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further incorporate various elements in the construct taught by Catchpole, including an SV40 enhancer sequence, intron A of the rat insulin gene and a rabbit beta-globin gene. One would have been motivated to do so because the prior art

teaches that such incorporation leads to successful or enhanced expression of polypeptides. There would have been a reasonable expectation of success, given the prior art demonstrates such success and the underlying techniques are widely known and commonly used as shown by the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to further incorporate various elements in the construct taught by Catchpole, including the known sAg/preS2 combination taught by Thudium. One would have been motivated to do so in order to express this known combination as a substitute antigen. There would have been a reasonable expectation of success, given the underlying techniques are widely known and commonly used as shown by the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to further purify the constructs taught by Catchpole. One would have been motivated to do so for the gain of optimizing results and minimizing contamination. There would have been a reasonable expectation of success, given the underlying techniques are widely known and commonly used as shown by the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a sequence encoding the human tissue plasminogen activator secretion signal sequence in the construct taught by Catchpole. One would have been motivated to do so for the advantage of purifying and preparing the expressed protein as a vaccine in Drosphila. There would have been a reasonable expectation of success because this signal peptide is well known and commonly used as demonstrated by the prior art.

The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of WO 02/36792 (hereinafter as "Catchpole", published 5/10/2002-cited by IDS), WO 02/031137 (hereinafter as "Thudium"-cited by IDS), Li et al. (Gene Therapy, 2001-see form 892), US Patent 6165477 (hereinafter as "Ivy"), Palmiter et al. (*PNAS*, 1991) as applied to claims 85-93, 96-102 and 116 above, and further in view of Scharton-Kersten et al. (*Infection and Immunty*, 2000-see form 892) as further evidenced by Moriarty et al. (*PNAS*, 1981-see form 892), Dean et al. (*Expt. Cell Res.*, 1999-see form 892), PGPUB 20030124523 (hereinafter as "Asselbergs", see form 892) and PGPUB 20030175711 (hereinafter as "Renner"; see form 892).

The claim is further drawn to a composition of claim 102 which further comprises an additional construct comprising a coding sequence which encodes a polypeptide which an ADP ribosylating bacterial subunit A and B (elected species I).

The combination of Catchpole, Thudium, Li et al., Ivy and Palmitter et al. (as further evidenced by Moriarty et al., Dean et al., Asselbergs and Renner) teach (in part): a nucleic acid construct comprising:

(i) a chimeric promoter sequence which comprises:

(a) an hCMV immediate early promoter sequence;

(b) exon 1 and at least a part of exon 2 of the hCMV major immediate early gene; and

(c) a heterologous intron provided in place of the intron A region of the hCMV major immediate early gene;

(ii) a coding sequence in operable linkage with the chimeric promoter;

(iii) a non-translated leader sequence which is selected from the HBVpreS2 antigen sequence, HBV e-antigen sequence and HSV type 2gD antigen sequence and which is in operable linkage with the chimeric promoter; and

(iv) an enhancer sequence which is derived from a 3' untranslated region (UTR) of a HBsAg sequence or of a simian CMV immediate early gene sequence, which is in operable linkage with the chimeric promoter and which is downstream of the coding sequence.

The combination of Catchpole, Thudium, Li et al., Ivy and Palmiter (as further evidenced by Moriarty et al., Dean et al., Asselbergs and Renner) does not teach a composition of claim 103 which further comprises an additional construct comprising a coding sequence which encodes a polypeptide which an ADP ribosylating bacterial subunits A and B (elected species I).

Scharton-Kersten et al. disclose that a bacterial LT composed of A and B subunits and the ADP-ribosylation activity have known adjuvant function (p. 5308, col. 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate other constructs comprising sequences encoding polypeptides known to have adjuvant activity, such as ADP ribosylating bacterial subunits A and B, in the composition disclosed by Catchpole, Thudium, Li et al., Ivy and Palmiter (as further

evidenced by Moriarty et al., Dean et al., Asselbergs and Renner). One would have been motivated to do for the gain of optimizing results (i.e. increase an immune response). There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used as shown by the prior art references applied. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 85-93, 96-103, 109-113, 116, 124-128 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 115-123, 126, 132-133, 137-156 of copending Application No. 11/815, 278. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to nucleic acid constructs that comprise similar elements including a chimeric promoter, encoded viral antigens, HBVpreS2 sequence, a 3' UTR sequence from a simian CMV immediate early gene sequence, ADP ribosylating bacterial toxin subunits, rat insulin gene intron A sequence, carrier particles which are gold particles and uses thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is

(571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Supervisory Patent Examiner, Art Unit 1648